Q2 Marketing Research, Inc.

May 24, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Dockets Management Branch:

I would like to request 20 minutes of time to speak at the FDA Regulation of OTC Drug Products Hearing which is being held on Wednesday, June 28 and Thursday, June 29, 2000 at the Holiday Inn in Gaithersburg, Maryland.

My name, addresses and telephone numbers are:


Stephen J. Hellebusch, Ph.D.
President
Q2 Marketing Research, Inc.
1009 Delta Avenue
Cincinnati, OH 45208-3103

Phone: 800-871-6922
Fax: 513-871-6996

email: q2@eos.net


I have no affiliation and no sponsor (other than Q2 Marketing Research, Inc.), just a long-term interest in the area of label comprehension testing in prescription-to-nonprescription switches. A brief summary of my presentation points accompanies this letter.

I understand that you will be accepting requests until June 2, and I look forward to hearing from you shortly after that date.

Sincerely,

Stephen J. Hellebusch, Ph.D.

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**Outline of Label Comprehension Study Talk**
**Stephen J. Hellebusch, Ph.D.**

1. Brief introductory credentials and comment:

   - Doctorate in Experimental Psychology
   - 20+ years experience in marketing research
   - Conducting research with both consumers and professionals
   - Have conducted many label comprehension studies, including a number submitted as part of NDAs

   Here voluntarily, without compensation.

2. Both good scientists and good business professionals make decisions based on data.

3. Label comprehension testing is a valid way to deal with some difficult decisions.

   In trying to deal with issues surrounding how well consumers comprehend certain aspects of a label, an actual test is developed. This is analogous to the manner in which students are tested in academic settings, and has a certain amount of face validity simply because of that.

   If some mechanism is included in the testing that enables one to relate test results to the current marketplace, such as including some type of control or comparator in the study, a logical validity can be achieved.

4. Label testing is an iterative process.

   A. Typically, a label is developed by those who know the product very well, and some attempt is made to make the label understandable to the target consumer. An excellent first step is to conduct qualitative research, and see how consumers react to the first draft label.

   B. This approach can be expanded by using qualitative research to develop the testing vehicle as well; in other words, "test the test", and make as certain as possible that the questions are unbiased and well understood.

   C. The next step is to conduct quantitative research. Most important in this respect is defining the objectives. Core communication messages concerning the product, those ones essential to a switch, must be defined. For example, the objective of one of the studies I have conducted was to make certain that a certain population understood that they were not to use the product, so intent to heed and the reasons for that intent were obtained from a broad-based sample of this target group.

The objectives drive the research, so creating general rules is difficult. Every switch is different. However, there are a few general considerations.

In constructing a test, make sure questions are fair and unbiased, and of various types e.g., open-ended and closed-ended

Include subjects with relatively low literacy levels in the sample, so that their comprehension can be addressed.

D. Since it is iterative, the process does not stop after a label is used in an Actual Use Test. Realistically, there may be several quantitative studies during/after Actual Use to improve the label.

5. Current OTC labels are good, but can probably be improved. However, perfection is not possible. Some small percentage of consumers either are so uninvolved in the research process they are not paying attention, or they are toying with the researcher.

   In a small research project, I once asked 545 consumers to give their exact age, at the start of and at the end of a 15-minute telephone interview.

   6% changed ages
   - 4% became one year older, or one year younger
   - 2% changed more than that

6. Since this is so, there is no agreed-upon comprehension standard that the label's communication points need to meet. Judgment can be made based upon the likely consequences of a lack of understanding. For example, if 25% of consumers misunderstand the name of the active ingredient, that may be less serious than if 15% misunderstand the product dosage.

7. In summation, since label comprehension testing is valid, it should be a key part of label development, and can provide the data to help both scientists and business professionals make good decisions.

**Butler, Jennie C**

**From:** Stephen J. Hellebusch [Q2@eos.net]
**Sent:** Wednesday, May 24, 2000 3:50 PM
**To:** fdadockets@oc.fda.gov
**Subject:** Regulation of OTCs Hearing


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